

HL7 SPL Working Group Process Communication Forum Telecon
Wednesday, Oct 20, 2010

Check out the SPL Working Group WIKI @:
<http://spl-work-group.wikispaces.com>

Questions on SPL:

ER/DL regulatory questions? Send to edrls@fda.hhs.gov

SPL technical questions? Send to spl@fda.hhs.gov

UNII or SRS questions? Send to fda-srs@fda.hhs.gov

Agenda:

HL7 ballot on SPL r5 Implementation Guide

The "Structured Product Labeling Release 5 Implementation Guide for FDA Establishment Registration, Listing, and UDI Submission" document was successfully balloted on the HL7 October ballot cycle.

With no negative comments, the RCRIM Working Group reviewed the document changes uploaded by Gunther Schadow. Gunther provided a comparison of what was balloted vs. what he uploaded in the comments.

New SPL Implementation Guide

http://wiki.hl7.org/images/d/d2/SPLr5_IGv1.0_-_new.pdf

Comparison to previous revision:

http://wiki.hl7.org/images/3/3f/Compare_-_SPLr5_IGv1.0_-_new.pdf

Previous SPL Implementation Guide

http://wiki.hl7.org/images/c/c0/SPLr5_IGv1.0_-_orginal.pdf

SPL Workgroup Devices meeting tomorrow 10:30 Eastern Time. Gunther will be going through the Implementation Guide and demonstrating Xforms. Note: Stylesheet not yet available for R5.

Contact Myron if you'd like a bit more information myron.finseth@medtronic.com.

Updates from ER/DL meeting (when a drug is considered listed, etc) [extracted from ER/DL minutes]

- There are multiple potential meanings/needs for being “listed” – import, NDC directory
- If you put in a future date, the SPL will not get posted to the Daily Med or on the NDC directory – until that date. But the file is available to customs staff to use in managing imports.
- NDC directory: if there is a problem with it not appearing on the NDC, send an email to the DRLS email.
- Import: Import staff can access the files out of the eLIST system earlier than some postings to DailyMed or to NDC Directory.
- CMS: uses only those NDC codes that are on NDC directory.
- Dragan submitted an SPL for PLAIR with date of 2020 so that the API would come into the country. They assumed that it was drug listed because customs let the API into the country.
- Prior to Launch PLAIR are being managed in 2 ways

One way: send in SPL to drug list with a future market start date.

Second way: tell them you will drug list at approval.

- There are > 8000 Establishment Registrations in eList
- The ER/DL subteam is collecting questions in preparation for another Q&A session with DRLS. If you have questions you’d like to submit (not company-specific!), send them along to Pat @ COWALL-HANOVER_PATRICIA_L@LILLY.COM. A time for the next Q&A session tbd.

Upcoming OTC Q&A discussion (UNII inactive ingredients and other topics)

- Recently there have been a few questions regarding listing of inactive ingredients in OTC drug product SPL files as well as import issues. **Huascar Batista** (FDA Office of Compliance) and **Lonnie Smith** (FDA Data Standards Council) have agreed to participate on the next SPL **OTC sub-team call November 8th at 1:00 pm ET** for discussion with sub-team members. They will be addressing questions related to imports drug registration and listing issues.

If you have OTC questions you’d like to submit (not company-specific!), send them along to Marcia @ mhoward@chpa-info.org by Tuesday, October 26. All questions will be provided to FDA ahead of time.

More SPL renditions on DailyMed

- SPL for OTC Monograph products now available on DailyMed. DailyMed now has over 16,000 SPL. If you'd like to make a public predication on when DailyMed will hit 20000 SPL, send it along to Terry or MaryBeth.

Other Questions / Issues

- Image difficulties: <http://spl-work-group.wikispaces.com/Images> . If you need more assistance, contact SPL@fda.hhs.gov. We'll post any other tips and advice on image provision on the WIKI.
- Postings of SPL to web repository
<http://www.accessdata.fda.gov/spl/data/rootID/rootID.xml> will soon be under 48 hours. If your file seems not to be accessible at this location, send a note to SPL@fda.hhs.gov with the rootid. Ask that the file be activated.

Next meeting scheduled for:

Wednesday, Nov 3, 2010

Time: 1:00-2:30 ET

Dial-in info: number 1-877-423-2663 PIN# 517342

- Minutes of previous Process Team meetings are here:
<http://spl-work-group.wikispaces.com/Process+Communications+Forum>